

November 14, 2024

**BY CM/ECF**

Hon. Patti B. Saris  
United States District Court for the District of Massachusetts  
John Joseph Moakley Courthouse  
1 Courthouse Way, Suite 2300  
Boston, Massachusetts 02210

**Re:** *BAGLY v. U.S. Dep't of Health and Human Services, et al.*, No. 1:20-cv-11297

Your Honor:

Plaintiffs submit this letter pursuant to the Court's invitation at the November 7, 2024 hearing in the above-captioned case. This submission addresses points raised in Defendants' reply brief in support of their suggestion of mootness as well as issues identified during the recent hearing.

**I. The Court May Grant Effectual Relief To Plaintiffs.**

"[A] case 'becomes moot only when it is *impossible* for a court to grant any effectual relief whatever to the prevailing party.'" *Chafin v. Chafin*, 568 U.S. 165, 172 (2013) (emphasis added) (quoting *Knox v. Serv. Emps. Int'l Union, Loc. 1000*, 567 U.S. 298, 307 (2012)). Defendants do not meet that standard because the relief that Plaintiffs seek remains available. Plaintiffs seek an order "set[ting] aside and vacat[ing] the Rollback Rule;" "declar[ing] that the Rollback Rule is unauthorized by, and contrary to" law; and "permanently enjoin[ing] the implementation of the Rollback Rule." Am. Compl. (ECF No. 18) at 106. The Court may grant that relief even though HHS has promulgated a new rule interpreting Section 1557.

*Vacatur*. Plaintiffs seek, among other forms of relief, the vacatur of the Rollback Rule. *See* Am. Compl. (ECF No. 18) at 106. That result will award effectual relief because it will set aside the unlawful agency action that has caused ongoing injury to Plaintiffs for more than four years now.

As Plaintiffs' counsel explained at oral argument, and as discussed more thoroughly in Part II, major components of the Rollback Rule are still in effect because a sister court has issued a nationwide stay of the effective date of the entire definition of "on the basis of sex" in the 2024 Rule. Order at 4, *Texas v. Becerra*, No. 6:24-cv-00211, Doc. No. 41 (E.D. Tex. Aug. 30, 2024). Because the 2024 Rule expressly states that the Rollback Rule "remains in effect, save for the parts enjoined or set aside by courts, until the effective date of this final rule,"<sup>1</sup> the Rollback Rule's prohibition of discrimination on the basis of sex, 45 C.F.R. § 92.2(a) & (b)(2) (2020) (85 Fed. Reg. 37,244)—which Plaintiffs allege unlawfully and arbitrarily excludes protections for gender identity, sexual orientation, pregnancy, termination of pregnancy, and sex stereotyping—remains in effect and presently governs HHS enforcement of Section 1557.

It is well-established that an order setting aside agency action restores the status quo ante. A similar pattern played out with rules implementing the Affordable Care Act's contraceptive coverage requirement, which requires health plans to cover all FDA-approved contraceptive methods without cost-sharing. *See DeOtte v. Azar*, 393 F. Supp. 3d 490, 498 (N.D. Tex. 2019), *vacated on other grounds and remanded*, *DeOtte v. State*, 20 F.4th 1055, 1064 (5th Cir. 2021). First, the relevant agencies issued rules interpreting the statute consistent with the Obama administration's view of the law. *Id.* at 496. Following a change in administration, the agencies

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<sup>1</sup> 89 Fed. Reg. 37,522, 37,523 (May 6, 2024).

issued new final rules reinterpreting those same statutory provisions consistent with the Trump administration's view of the law. *Id.* at 497–98. Courts preliminarily enjoined the Trump administration's rules, *id.* at 498 (citing to *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019) (order granting nationwide preliminary injunction)); *see also California v. HHS*, 351 F. Supp. 3d 1267, 1300 (N.D. Cal. 2019) (same as to plaintiff states), and a group of plaintiffs opposed to the contraceptive coverage requirement challenged the Obama administration's rules, which had then taken effect as a result of the preliminary injunctions, *id.* at 498–99. A federal district court then entered the plaintiffs' requested permanent injunction against enforcement of those Obama-era rules. *Id.* at 513. Throughout the litigation, both the district court and the appellate court recognized that the Obama administration rules that the plaintiffs challenged were indeed the governing regulations because the Trump administration's rules had already been preliminarily enjoined by court order. *Id.* at 498; 20 F.4th at 1062 (preliminary injunctions against the Trump rules "thereby re-instat[ed] enforcement of the [Obama] Rules").

The Fifth Circuit is not alone in that understanding. This Court's decision in *Oxfam Am., Inc. v. United States Sec. & Exch. Comm'n*, 126 F. Supp. 3d 168 (D. Mass. 2015), for example, similarly held that another court's vacatur of an agency rule "restore[d] the status quo ante" and permitted the district court to award relief as though the agency had never acted at all. *Id.* at 172. In that case, the Securities and Exchange Commission issued a rule that was then vacated by the D.C. district court. *Id.* at 171 (citing *Am. Petroleum Inst. v. S.E.C.*, 953 F. Supp. 2d 5, 25 (D.D.C. 2013)). The *Oxfam* plaintiffs then sued in the District of Massachusetts to compel agency action under Section 706(1) of the Administrative Procedure Act (APA). 126 F. Supp. 3d 168. In this Court, the agency argued that its prior rule—which had never taken effect due to the D.C. litigation—meant that the agency "ha[d] not in fact 'unlawfully withheld' action." *Id.* at 172. This Court rejected that argument, reasoning that "the [D.C.] district court's decision to vacate the final disclosure rule simply returned matters to where they stood before." *Id.*

The cases are clear: where an agency action is found deficient and vacated or otherwise enjoined, the status quo prior to the agency's action is restored. *See, e.g., Am. Acad. of Pediatrics v. U.S. Food & Drug Admin.*, 330 F. Supp. 3d 657, 664 (D. Mass. 2018) (ordering FDA to comply with statutory deadline requiring issuance of rule following vacatur of earlier rule, and rejecting agency's argument that agency's promulgation of nullified rule cured the statutory violation); *see also, e.g., United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) ("[V]acatur of the 2018 Amendment automatically resurrects the 2017 Standard. The 2018 Amendment modifies the terms of the 2017 Standard and so vacatur of the 2018 Amendment simply undoes those modifications."); *Nat'l Venture Cap. Ass'n v. Duke*, 291 F. Supp. 3d 5, 21 (D.D.C. 2017) (observing that "vacating the Delay Rule would simply" "restore the status quo ante" and therefore "allow the IE Final Rule to take effect"); *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) ("The effect of invalidating an agency rule is to reinstate the rule previously in force.").

This Court, like all of the others cited, can therefore grant effectual relief to Plaintiffs even though HHS has promulgated a new rule interpreting Section 1557. As explained above, the challenged portions of the 2024 Rule largely have not taken effect, which means the Rollback Rule's provisions remain effective. This Court may accordingly order vacatur of those provisions of the Rollback Rule, which will restore the status quo ante—*i.e.*, the robust nondiscrimination

protections required by Section 1557 and recognized by the 2016 Rule—while the many challenges to the 2024 Rule continue to be litigated.

*Declaratory Judgment.* Plaintiffs also seek declaratory relief. *See* Am. Compl. at 106. This Court’s grant of Plaintiffs’ request for declaratory relief would also redress Plaintiffs’ injuries.

In *Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022), a district court entered a declaratory judgment declaring unlawful an agency guidance document interpreting Section 1557. At issue in *Neese* was a May 2021 public notice signaling the Biden administration’s intent “to interpret the definition of ‘sex discrimination’ under Section 1557 and title IX to include gender identity and sexual orientation.” 89 Fed. Reg. 37,522, 37,574 n.118 (May 6, 2024). The district court held that the agency guidance reflected a misapplication of *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020), entered a declaratory judgment to that effect, and extended relief to a class of health care providers subject to Section 1557. *Neese*, 640 F. Supp. 3d at 676–87; *see also id.* at ECF Nos. 70 & 71 (N.D. Tex. Nov. 22, 2022)). HHS then acknowledged the effect of that decision in subsequent rulemaking, explaining that “[t]he Department is not applying the challenged interpretation to members of the *Neese* class pending the appeal.” 89 Fed. Reg. at 37,574 n.108.

Just as a declaratory judgment was effective relief for the *Neese* plaintiffs, so too will a declaratory remedy be effectual for Plaintiffs here. And “the virtually unflagging obligation of the federal courts to exercise the jurisdiction given them” is not outweighed by “concerns about piecemeal litigation,” which “weigh in favor of dismissal only if there is some ‘exceptional basis’ for dismissing one action in favor of the other.” *KPS & Assocs., Inc. v. Designs By FMC, Inc.*, 318 F.3d 1, 10–11 (1st Cir. 2003) (internal quotation marks and citations omitted). No exceptional basis exists here: If HHS comports its conduct with a declaration invalidating a sub-regulatory interpretive document, it must also comply with a declaration issued in litigation over an agency rule that continues to carry the force of law. Because the challenged rule’s provisions have “impacted, and will continue to impact” Plaintiffs on an ongoing basis, there is a live controversy of “sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Eaton v. Veterans Inc.*, 435 F. Supp. 3d 277, 281 (D. Mass. 2020) (quoting *Am. Civil Liberties Union of Mass. v. U.S. Conference of Catholic Bishops*, 705 F.3d 44, 53–54 (1st Cir. 2013)).

Defendants argue the *Neese* judgment precludes this Court from granting relief, *see* ECF No. 171 at 7 n.2, but that is wrong both as a practical and legal matter. Because the administrative action at issue in *Neese* was agency guidance reflecting the Biden administration’s views of Section 1557, it is not yet clear that the guidance—or the district-court judgment declaring it unlawful—will survive the coming change in agency leadership. Even if the *Neese* judgment continues to bind the agency in 2025, though, the order, by its terms, is limited to the certified class of health care providers—not insurers. For that reason, Defendants cannot contend that *Neese* would render a declaration by this Court ineffectual; a declaratory remedy would, for example, redress Plaintiffs’ injuries by holding unlawful the Rollback Rule’s interpretation of Section 1557 allowing discriminatory benefit design.

## **II. Plaintiffs’ Summary Judgment Motion Identifies Live Claims.**

Plaintiffs’ Partial Motion for Summary Judgment (ECF No. 141) remains viable.

There is only one aspect of the Rollback Rule that Plaintiffs challenge that has actually been superseded by the 2024 Rule: the agency’s interpretation of Section 1557’s definition of “health

program or activity.” There is no court order currently enjoining this provision of the 2024 Rule. *See* ECF No. 176 at 1–3, 130 (order providing that “a § 705 stay should apply nationwide but only as to the portions of the Final Rule challenged here”).<sup>2</sup>

All the other portions of the Rollback Rule that Plaintiffs continued to challenge on summary judgment remain in effect because court orders have enjoined the application of changes made by the 2024 Rule. *See* Pls’ Mootness Br. (ECF No. 167) at 6–12. For example, the Rollback Rule’s treatment of discrimination on the basis of sex, including gender identity, sexual orientation, pregnancy, and abortion, continues to harm Plaintiffs. Plaintiffs continue to challenge—and the Court may address—the following aspects of the Rollback Rule:

1. Plaintiffs’ claim that the Rollback Rule’s interpretation of “on the basis of sex”, codified at 45 C.F.R. §§ 92.2(a) & (b)(2) (2020), and discussed at 85 Fed. Reg. 37,160, 37,162, 37,178–180, 37,244, violates Section 1557 and is contrary to law. *See* Pls’ Partial MSJ Br. (ECF No. 141) at 17–22.
2. Plaintiffs’ claim that the Rollback Rule’s interpretation of “on the basis of sex”, codified at 45 C.F.R. §§ 92.2(a) & (b)(2) (2020), and discussed at 85 Fed. Reg. at 37,162, 37,178–180, 37,244, is arbitrary and capricious. *See* Pls’ Partial MSJ Br. at 22–26.
3. Plaintiffs’ claim that the Rollback Rule’s incorporation of cherry-picked exemptions from Title IX—the “religious exemption” and “abortion-provision-and-coverage exemption”—into the health care context, codified at 45 C.F.R. § 92.6(b) (2020) and discussed at 85 Fed. Reg. at 37,162, 37,192–193, 37,207–208, 37,245, is contrary to law. *See* Pls’ Partial MSJ Br. at 26–30.
4. Plaintiffs’ claim that the Rollback Rule’s incorporation of the Title IX exemptions, codified at 45 C.F.R. § 92.6(b) (2020) and discussed at 85 Fed. Reg. at 37,162, 37,192–193, 37,207–208, 37,245, is arbitrary and capricious. *See* Pls’ Partial MSJ Br. at 30–34.
5. Plaintiffs’ claim that the Rollback Rule is arbitrary and capricious because it evinces animus toward, and negative stereotypes about, transgender people and their health care. *See* Pls’ Partial MSJ Br. at 42–47; *see, e.g.*, 85 Fed. Reg. at 37,187.
6. Plaintiffs’ claim that HHS failed to consider an important aspect of the problem: the likely risk of discrimination—motivated by bias—against LGBTQI+ persons, women, and pregnant people in accessing health care. *See* Pls’ Partial MSJ Br. at 47–49; *see, e.g.*, 85 Fed. Reg. at 37,180 n.90–91, 37,189, 37,193, 37,222.
7. Plaintiffs’ claim that HHS failed to conduct an adequate regulatory impact analysis by disregarding the costs to patients, *see, e.g.*, 85 Fed. Reg. at 37,165, 37,180, 37,192–193, 37,199–200, 37,229, misrepresenting costs to the health care industry, *see, e.g.*, 85 Fed. Reg. at 37,160, 37,162, and failing to account for costs transferred to the States due to emboldened discrimination resulting from the Rule, *id.* at 37,163. *See* Pls’ Partial MSJ Br. at 49–50.

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<sup>2</sup> Even if this particular claim is nominally moot, Plaintiffs believe that it is still justiciable because exceptions to the mootness doctrine apply. *See* Pls’ Mootness Br. at 12–20.

Moreover, although Plaintiffs have not yet moved for summary judgment on their Equal Protection Clause Claim, it too is still live.

### III. The Rollback Rule's Compliance With The Statute Is A Merits Question.

Plaintiffs have alleged that the Rollback Rule violates Section 1557 and is therefore unlawful under the APA.<sup>3</sup> The Rollback Rule pulled the agency into a cramped construction of Section 1557 that finds no basis in the statutory text.

At the hearing, Defendants suggested that the Rollback Rule does not harm Plaintiffs because it merely parrots the statute. That is wrong. Plaintiffs have challenged the Rollback Rule's unlawful interpretation of Section 1557's protections against sex discrimination and seek to restore the straightforward reading of Section 1557 that flows from the statute itself.

Not only does Defendants' view ignore Plaintiffs' merits arguments that several provisions of the Rollback Rule are contrary to Section 1557, Pls' Partial MSJ Br. at 16–22, 26–29, 34–42, it also disregards Plaintiffs' 107-page Amended Complaint and multiple declarations detailing at length the harm wrought by the Rollback Rule, *see, e.g.*, Am. Compl. ¶¶ 189–264; Pls' Partial MSJ Br. at 6–10 & Exs. A–C, E–I; the more than 134,000 commenters who opposed the Rule, Am. Compl. ¶ 166, Pls' Partial MSJ Br. Ex. D; and this Court's own decision finding that Plaintiffs adequately alleged injury resulting from the Rollback Rule's treatment of multiple provisions related to sex discrimination, Mot. Dismiss Order (ECF No. 63). Moreover, it ignores hornbook principles of administrative law that the preamble and regulatory context inform the meaning of ambiguous regulatory text. *See Rucker v. Lee Holding Co.*, 471 F.3d 6, 12–13 (1st Cir. 2006); *see also Duke Energy Progress, LLC v. FERC*, 106 F.4th 1145, 1154 (D.C. Cir. 2024); *City of Las Vegas v. Fed. Aviation Admin.*, 570 F.3d 1109, 1117 (9th Cir. 2009).

The Rollback Rule repealed the 2016 Rule's robust definition of “on the basis of sex,” thus deleting explicit protections against discrimination based on gender identity, pregnancy, termination of pregnancy, and sex stereotyping. 85 Fed. Reg. at 37,178. And the Rollback Rule's preamble—which is pervaded by anti-transgender and anti-abortion animus, *see, e.g.*, *id.* at 37,178–180, 37,192–93, 37,222—repeatedly disclaims that “on the basis of sex” encompasses gender identity or sexual orientation, *e.g.*, *id.* at 37,178–80, 37,194; refuses commenters' requests to clarify that it reaches the full scope of pregnancy-related discrimination, including that related to miscarriage and abortion, *id.* at 37,192–93; and explicitly states that Section 1557 never requires the provision of abortion care or coverage, even in cases of medical emergency, *id.* at 37,193. Indeed, the Rollback Rule's incorporation of Title IX's religion and abortion-provision-and-coverage exemptions, which gut Section 1557's protections against sex discrimination for pregnant and transgender people, are nowhere found in the statutory text. Pls' Partial MSJ Br. at 26–29. Defendant is thus wrong to suggest that the Rollback Rule's prohibition on sex discrimination simply reverts to the statute.

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<sup>3</sup> While it is true that Section 1557 encompasses a private right of action, enforcement of its requirements against private defendants alone is no silver bullet. Administrative interpretation is an important parallel element of the overall enforcement scheme. Rendering the role of the HHS Office of Civil Rights a nullity would force potential plaintiffs to undertake costly litigation or represent themselves *pro-se*, and victims of discrimination face a vast array of obstacles that make such enforcement easier said than done. *See* Hon. Jed Rakoff, *Why You Won't Get Your Day in Court*, The N.Y. Review (Nov. 24, 2016), available at <https://perma.cc/M4GR-CNX6>.

Whatever may be said of these interpretive questions, Defendants' willingness to engage them at a hearing focused on mootness simply underscores Plaintiffs' position: The merits are ripe for resolution. These questions of law are at the core of Plaintiffs' Amended Complaint, and they should now be litigated to final judgment. The agency should be directed to respond to Plaintiffs' summary judgment motion expeditiously, including the statutory interpretation questions raised in that briefing.

#### IV. Additional Updates In Related Cases

Finally, Plaintiffs update the Court on developments in matters cited in their recent Notice of Case Developments (ECF No. 176), both of which underscore the importance of this litigation proceeding in order to remedy Plaintiffs' ongoing harm. First, the U.S. District Court for the Southern District of New York entered an order dismissing *New York v. U.S. Department of Health and Human Services*, No. 20 Civ. 5583 (AKH), Doc. 196 (S.D.N.Y. Nov. 11, 2024), an APA challenge to the Rollback Rule. The Court reasoned that because plaintiffs there did not point to "any specific provision of the 2020 Rule that is currently in force," it concluded there was no live controversy. *Id.* at 2. Here, however, as explained in Part II, Plaintiffs have pinpointed precisely the provisions of the 2020 Rule that continue to govern and continue to cause them harm.

Second, the U.S. District Court for the Middle District of Florida issued an order this week requiring parties to file status updates by November 15 regarding "the likelihood of mootness given a pending change in administration" in one of the challenges to the 2024 Rule. *See Florida v. U.S. Department of Health and Human Services*, No. 8:24-cv-01080-WFJ-TGW, Doc. 58 (M.D. Fla. Nov. 12, 2024). The order acknowledges what Plaintiffs have argued here. HHS changes interpretations of Section 1557 too frequently to allow the statute's meaning to be fully litigated; proving that point, the *Florida* court recognizes the agency may soon abandon its current position yet again. The continuing regulatory whipsaw is all the more reason the exceptions to mootness counsel against dismissal here (should the Court find any claim moot at all) under the doctrines of capable of repetition, yet evading review and voluntary cessation. *See* Pls' Mootness Br. at 16–17.

Respectfully submitted,

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